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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/245,025	02/05/1999	GARY F. GERARD	0942.4330003	4443

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EXAMINER

NASHED, NASHAAT T

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 05/07/2002

19

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.  
**09/245,025**Applicant(s)  
**Gerard et al.**Examiner  
**Nashaat T. Nashed**Art Unit  
**1652**

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on Feb 14, 2002
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 117-213 is/are pending in the application.
- 4a) Of the above, claim(s) 149, 157, 165, and 176 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 117-148, 150-156, 158-164, 166-175, and 177-213 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 1-6 6) ☐ Other:

The application has been amended as requested in the communication filed February 14, 2002. Accordingly, claims 1-9, 22-25, 41-45, 81-88, and 116 have been canceled, and claims 117-213 have been entered.

Claims 117-213 are pending. Claims 149, 157, 165, and 176 are withdrawn from further for being drawn to non-elected subject matter, and claims 117-148, 150-156, 158-164, 166-175 and 177-213 are under consideration in this Office action.

Due to the size of the first Information Disclosure Statement filed May 5, 1999, most of the reference could not be found in the parent file, i.e., 09/064,057. If applicants wish for the references to be considered, they should refile a new set of references. Applicant may wish to contact the undersigned examiner directly to arrange for hand delivery of the missing references. Attached is 1449 wherein all the reference that were found are initialed.

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. Specifically, the application discloses several specific reverse transcriptases from several viruses and methods of their making as well as method of making mutants thereof. Neither the nucleic and/or amino acid sequences are found in the specification. The specification reference specific amino acid residues from supposedly an amino acid sequence without identifying the amino acid sequence with a sequence identification number, see for example page 57, lines 11 and 12. Another sequence on page 73, line 22, is not accompanied by a sequence identification number. The previously mention non-compliance with the sequence rule are intended to be an examples and not as an exhaustive list of non-compliance with the sequence rules. Applicants are required to bring their application to full compliance with the sequence rules.

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the

disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," *etc.*

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The following title is suggested: Composition of AMV-Reverse Transcriptase and Mutants Thereof.

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claims 148, 150-156, 158-164, 166-175, and 177-182 are objected to under 37 CFR § 1.75(d)(1) as being in improper form because the claim states an improper Markush groups. Compounds included within a Markush group must "(1) share a common utility and (2) share a substantial structural feature disclosed as being essential to that utility." (See MPEP § 803.02.) The specification defines the abbreviation ASLV reverse transcriptase as any reverse transcriptase from any one of the viruses listed on page 4, lines 1-10, which defines a Markush group. The various members of the Markush group in the claims are different chemical compound and do not share a common structural feature required for the stated utility, i. e., the reverse transcriptase activities.

Claim 145, 172, and 204 are objected to under 37 CFR § 1.75(d)(1) as being in improper form because the claim states an improper Markush groups. Compounds included within a Markush group must "(1) share a common utility and (2) share a substantial structural feature disclosed as being essential to that utility." (See MPEP § 803.02.)

Claims 120-124, 126-129, 134, 136-138, 140-143, 150, 158, 166, 177, 184, 198, and 208 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The parent claims are drawn to compositions of viral reverse transcriptase, the wild-type. Claims 120-124, 126-129, 134, 136-143, 150, 158, 166, 177, 184, 198, and 208 expand the scop of the claim from which they depend to include mutants and fragments.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 120, 121, 126, 134, 140, 148, 150-156, 158, 159-175, 177-213 and 127-148 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Regarding claims 120, 126-129, 134, 136-137, 140-143, 150, 158, 166, 177, 184, 191, 198, and 208 are directed to a recombinant compositions and kit comprising a mutant of the  $\beta$ -subunit, named  $\beta p4$ , from any Avian Sarcoma-Leukosis Virus (ASLV) and other enzymatically active mutants and fragment thereof. The specification, however, only provides a single representative species for the  $\beta$ -subunit of RSV reverse transcriptase which forms a heterodimer with the  $\alpha$ -subunit of RSV reverse transcriptase to produce a heterodimer with substantially reduced RNase H activity. There is no disclosure of any structure for any reverse transcriptase from any source or their mutants. The specification also fails to describe additional representative species of the so called  $\beta p4$  subunit by any identifying structural characteristics or properties other than forming a heterodimer with reduced RNase activity relative to the wild-type. Given this lack of additional representative species as encompassed by the claims, Applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize Applicants were in possession of the claimed invention.

Also, regarding claims 148, 150-156, 158, 159-175, 177-213 and 127-148 are directed to a preparation of any ASLV reverse transcriptase from any biological source with at least 30,000 units per milligram using any substrate assaying any activity of any reverse transcriptase. Claim 121 and 135 are directed to a composition containing more than one reverse transcriptases wherein the reverse transcriptases have different pause sites. The specification, however, only provides a single representative species for the RSV reverse transcriptase. There is no disclosure of any structure for any reverse transcriptase from any source or their mutants and enzymatically active fragments, specifically those listed on the top of page 4. Also, there is no disclosure of any pause site for any of the mentioned reverse transcriptases in the specification. The specification also fails to describe additional representative species of the claimed representative species by any identifying structural characteristics or properties other than having specific activity

of at least 30,000 units per milligram without identifying the activity to be measured and what constitute a unit of activity. Given this lack of additional representative species as encompassed by the claims, Applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize Applicants were in possession of the claimed invention

Claims 117-148, 150-156, 158-164, 166-175 and 177-213 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following are the reasons for the rejections:

- (a) claims 119, 120, 125, 126, 133, 134, 139, 140, 148-156, 158-164, 166-171, 175, 177-203, 207-213 contain the undefined abbreviations ASLV and AMV. Abbreviations and acronyms must be defined at least once in the claims.
- (b) the phrases "ASLV reverse transcriptase" in claims 120, 126 134, 140, 148, 150-156, 158-164, 166-171, 175, 177-182; "specific activity ..... units per milligram" in claims 148, 151-156, 159-162, 164, 167-170, 178-181, 185-188, 190, 192-195, 197, 199-202, 207, and 209-212; and "one or more subunits" in claims 120, 126, 134, 140, 150, 158, 166, 177, 184, 191, 198, and 208 render the claims indefinite because the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. It is noted that ASLV, presumably, Avian Sarcoma-Leukosis Virus, reverse transcriptase is defined in the specification starting on last two lines on page 3, through line 6 on page 4, but the definition contains the clause "which includes but not limited to ...." that renders the claims indefinite. The specification and the claims do not define the activity or a unit of activity. Reverse transcriptases are multi functional enzymes, and known to have several activities that include RNA-directed DNA-polymerase, DNA-directed DNA-polymerase and RNase H activity. Since one of ordinary skill in the art would not know which one of said specific activities the claims are referring to and the meaning of unit of activity, the ordinary skilled in the art would not know the metes and bounds of the claimed invention. One or more subunit is considered indefinite because the enzymatically active form of the enzyme is a dimer and therefore there could not be more than two subunits per molecule of enzyme. For examination purposes: (i) ASLV reverse transcriptase is assumed to be the viral reverse transcriptase listed on the top of page 4; (ii) specific activity ..... units per milligram is assumed to mean enzymatically active preparation, and (iii) "one or more subunits" is assumed to mean homodimer containing two  $\alpha$ -AMV reverse transcriptase or two  $\beta$ -AMV reverse transcriptase; or heterodimer containing one of each the  $\alpha$ - and  $\beta$ -subunits of AMV reverse transcriptase.

- (c) the phrase "βp4 subunit" in claim 120, 126, 134, 140, 150, 158, 166, 177, 184, 198, and 208 is not structurally defined by the specification or the claims, and therefore, the claim is considered indefinite. For examination purposes.
- (d) The terms "reduced" in claims 122, 127, 136, 141 and "substantially reduced" in claim 123, 128, 137, 142 are a relative term which renders the claim indefinite. The terms "reduced" and "substantially reduced" are not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. For examination purposes only, the phrases are taken to mean "less RNase activity relative to the wild-type enzyme".
- (e) The phrases "working concentration" in claims 144, 177, 182, 189, 196, 203, and 213, "one or more terminating agents" in claim 145, 172, and 204; "dideoxynucleotide" in claim 146, 173, and 205 render the claims indefinite because the resulting claims do not clearly set forth the metes and bounds of the patent protection desired. The only terminating agent and "dideoxynucleoside" that are utilized by reverse transcriptase are 2',3'-dideoxynucleoside triphosphates. One of ordinary skill in the art would not expect dideoxynucleoside mono- and diphosphates to be substrates for reverse transcriptase and therefore, they are not expected to terminate the polymerization reaction on the template. The ordinary skill in the art would not know others and the specification does not teach any. For examination purposes only, the "terminating agent" and "dideoxynucleoside" are assumed to be dideoxynucleoside triphosphates. Since there is no reasonable meaning to be given for the phrase "working concentration", the phrase is ignored.
- (f) Claims 175 and 207 are drawn to a reverse transcriptase made by an incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted step is a purification of the reverse transcriptase from the culture of the host cell, after step (b) and before step (c) in each claim.
- (g) All other claims not mentioned in (a)-(f) are included in these rejection because they are dependent from rejected claims and do not correct their deficiencies.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 148, 150-156, 158-164, 166-171, 175, 177-203, 207-213 are rejected under 35 U.S.C. § 102(b) as being anticipated by Soltis *et al.* (see IDS: Proc. Natl. Acad. Sci. U. S. A. 1988, 85, 3372-3376).

Soltis *et al.* teach the expression separately of both the  $\alpha$ - and  $\beta$ -subunits of AMV-reverse transcriptase in *E. coli* host cell. They teach that the isolated  $\alpha$ - and  $\beta$ -subunits have a reverse transcriptase and function as homodimers, see abstract. They teach the construction of pRC23-p95 for  $\alpha$ -subunit and pRC23-p63 for  $\beta$ -subunit, see page 3372, right column, last two paragraphs, the purification and assay for the enzyme, see page 3373, right column (claims 26, 28, 33, 40, 117-122, 124, 125, 127-148). Since the claims are being interpreted as having any enzymatic activity of any one of the known activities of AMV-reverse transcriptase, the reference anticipate the claimed invention.

Claims 148, 150-156, 158-164, 166-171, 175, 177-203, and 207-213 are rejected under 35 U.S.C. § 102(b) as being anticipated by Yu (see IDS Reference: AR-26).

Yu *et al.* teach the commercial availability of AMV-reverse transcriptase from U. S. Biochemical Corp having a specific activity of 62,700 units/mg (claims 148, 150-156, 158-164, 166-171, 175, 177-203, and 207-213). It should be noted that an AMV-reverse transcriptase is considered to be the same chemical compound regardless of the method of its making. Applicants have the burden of distinguishing their invention from those of the prior art.

Claims 148, 150-156, 158-164, 166-171, 175, 177-203, 207-213 are rejected under 35 U.S.C. § 102(b) as being anticipated by the fact that AMV- and M-MuLV-reverse transcriptase are commercially available (see IDS Reference: AT-19).

Claims 148, 150-156, 158-164, 166-175, and 177-182 are rejected under 35 U.S.C. § 102(b) as being anticipated by U. S. Patent 5,244,797 ('797, Kotewicz *et al.*).

'797 teaches the cloning and expression of reverse transcriptases from retro viruses such as M-MLV, BLV, RSV and HIV-type 1, previously known as HTLV-type 1, see column 1 and 2. Also, they teach mutants which has RNA-directed DNA polymerase activity ranging from 17,500-350,000 units/mg, and substantially reduced and no detectable RNase activity, see column 18, Table 2. Also, they teach a kit comprising the reverse transcriptase and other material such as dideoxynucleoside triphosphates, buffer and oligo(dT) primer, and control RNA to be used as standard, see column 12, lines 16-30.



The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

Claims 148, 150-156, 158-164, 166-175, 177-213 are rejected under 35 U.S.C. § 103 as being unpatentable over either Soltis *et al.* in view of the state of the art at the time of the application was filed as exemplified by Chattopadhyay *et al.* [IDS: Protein Expression and Purification 3, 151-159 (1992)]

The teaching of Soltis *et al.* are summarized above.

Chattopadhyay *et al.* teach the expression and purification of HIV-1 reverse transcriptase and the purification of the heterodimer from the transformed *E. coli* (see the abstract and page 153, right column, last two paragraphs through page 154, right column, end of the first paragraph).

AMV-reverse transcriptase has been used extensively in biotechnology in the preparation of cDNA libraries and is a commercially viable product in the market place. Thus, one of ordinary skill in the art would have had the motivation at the time of invention to produce AMV-reverse transcriptase by a recombinant method. Thus, the ordinary skill in the art would have constructed a vector(s) comprising a nucleic acid sequence encoding

the  $\alpha$ - and  $\beta$ -subunits of AMV-reverse transcriptase, transform a host cell with said vector(s) and culture the host cell as taught by Soltis, and purify the enzyme to any specific activity that suits his/her purposes, i. e., to any specific activity of any desired activity, by well known methods in the prior art (claim 148, 150-156, 158-164, 175, 177-203, and 207-213). Also, the ordinary skill in the art would have been further motivated to coexpress the  $\alpha$ - and  $\beta$ -subunits in the same host cell to produce the heterodimer because the heterodimer have higher thermalstability, see the abstract of Soltis *et al.* Thus, the ordinary skill in the art would have constructed the pRC23-p95 and pRC23-p63 taught by Soltis and coexpress them in a single host cell to produce the heterodimer. In addition, one of ordinary skill in the art would be further motivated to construct a single vector comprising the coding sequences for both the  $\alpha$ - and  $\beta$ -subunits of AMV-reverse transcriptase under the control of the same promoter which would lead to the production of equal amount of the two subunits (claim 148, 150-156, 158-164, 175, 177-203, and 207-213). Once the ordinary skill in the art obtain the reverse transcriptase, he/she would have packaged it in a kit comprising buffers, primers of interest, one or more DNA polymerase to amplify the DNA product of the transcription, and one or more terminating agents for sequencing the product of the transcription (claims 172-174, and 204-206). Thus, the claimed invention was within the ordinary skill in the art to make and use at the time was made and was as a whole, clearly *prima facie* obvious.

Claims 148, 150-156, 158-164, 166-175, 177-213 are rejected under 35 U.S.C. § 103 as being unpatentable over the fact that AMV- and M-MuLv-reverse transcriptase are commercially available from Boehringer Mannheim Biochemical and U. S. Biochemical in view of the state of the art at the time of the application was filed as exemplified by Chattopadhyay *et al.* [IDS: Protein Expression and Purification 3, 151-159 (1992)].

The teaching of Chattopadhyay *et al.* is summarized above.

AMV-reverse transcriptase has been used extensively in biotechnology in the preparation of cDNA libraries and is a commercially viable product in the market place. The commercial preparation of AMV-reverse transcriptase may contain undesired enzymatic activities such as proteases or ribonucleases. Thus, one of ordinary skill in the art would have had the motivation at the time of invention to further purify the commercial preparation of AMV-reverse transcriptase by well known methods taught in the art such as that taught by Chattopadhyay *et al.* and preparative electrophoresis to homogeneity (claims 148, 150-156, 158-164, 175, 177-203, and 207-213). Once the ordinary skill in the art obtain the purified reverse transcriptase, he/she would have packaged it in a kit comprising buffers, primers of interest, one or more DNA polymerase to amplify the DNA product of the transcription, and one or more terminating agents for sequencing the product of the transcription (claims 172-174, and 204-206). Thus, the claimed invention

was within the ordinary skill in the art to make and use at the time was made and was as a whole, clearly *prima facie* obvious.

Claims 117-147 are rejected under 35 U.S.C. § 103 as being unpatentable over Aatsinki *et al.* in view the facts that AMV- and M-MuLV-reverse transcriptase are commercially available from Boehringer Mannheim Biochemical and U. S. Biochemical and the fact that HIV-1 reverse transcriptase and RSV-transcriptase are well known in the prior art of record, U. S. Patent 5,244,797 ('797), and in view of the state of the art at the time of the application was filed as exemplified by Chattopadhyay *et al.* [IDS: Protein Expression and Purification 3, 151-159 (1992)].

The teaching of the '797 patent are summarized above.

Aatsinki *et al.* provide one of ordinary skill in the art to use more than one reverse transcriptase in the transcription of RNA to DNA as they teach the use of two transcriptase activities, AMV-reverse transcriptase and *Thermus aquaticus* DNA-polymerase which have a reverse transcriptase activity to overcome the problems caused by pause sites. Thus, the ordinary skill in the art would have prepare a composition comprising a mixture of well known AMV-, RSV-, MMLV revers transcriptases including their mutants with reduced RNase activity such as those taught in the '797 patent which have different pause sites and utilize the composition in a method of constructing a cDNA library or formulate a kit comprising the composition described above in similar fashion to the kit taught in the '797 patent (claim 117-147). Thus, the claimed invention was within the ordinary skill in the art to make and use at the time was made and was as a whole, clearly *prima facie* obvious.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 148, 150-156, 158-164, 166-175, and 177-213 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 of U.S. Patent No. 5,244,797 (797). Although the conflicting claims are not identical, they are not patentably distinct from each other because they are claiming the same subject matter or an obvious variant thereof.

Claims 148, 150-156, 158-164, 166-175, and 177-213 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-84 of U.S. Patent No. 6,063,608 (608). Although the conflicting claims are not identical, they are not patentably distinct from each other because they are claiming the same subject matter or an obvious variant thereof.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nashaat T. Nashed, Ph. D. whose telephone number is (703) 305-6586. The examiner can normally be reached Monday, Tuesday, Thursday, and Friday from 9:00 a.m. to 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached on (703) 308-3804. The fax phone numbers for this Group are (703) 305-3014 and (703)308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Nashaat T. Nashed, Ph. D.  
Primary Examiner